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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,360	07/30/2001	Leroy E. Hood	P-IS 4627	2535

41552 7590 08/25/2005

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EXAMINER	
ZHOU, SHUBO	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,360	HOOD ET AL.	
	Examiner	Art Unit	
	Shubo (Joe) Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,8-16,30-32,34 and 36-82* is/are pending in the application.

4a) Of the above claim(s) *3 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6,8-16,30-32,34,36-44 and 46-82* is/are rejected.

7)☒ Claim(s) *1,2,4,6,8-16,30-32,34,36-44 and 46-82* is/are objected to.

8)☒ Claim(s) *1-4,6,8-16,30-32,34 and 36-82* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 2 May 05
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/17/05 has been entered.

Amendments

2. Applicants' amendment to the claims filed 5/17/05 is acknowledged. However, the amendment is not completely in compliance with 37 CFR 1.121 because the identifier "original" for claim 32 is not proper. The claim has obviously been currently amended. A correction of the identifier for the claim is requested.

Claims 1-4, 6, 8-16, 30-32, 34, and 36-82 are currently pending and under consideration except claims 3 and 45, which have been previously withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claim Rejections-35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 57-64, 66-73, and 75-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly added claims 57-64, 66-73, and 75-82 recite an "n" dimensional space where "n" is any of 5, 10, 20, 50, 100, 200, 500 and 1000. While the specification describes a 2-dimensional and 3-dimensional coordinates as in Figures 1 and 2, it does not describe a space of more than 3 dimensions. These limitations in the new claims are thus new matter.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-2, 4, 6, 8-16, 30-32, 34, 36-44, and 46-82 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1, 16 and 30 have been amended to recite "creating a multidimensional space of n dimensions, wherein n represents the number of molecules being

analyzed in a specimen" in step (a) of each claim. The metes and bounds of the limitation "n represents the number of molecules being analyzed are not clear. It is unclear what is meant by "the number of molecules being analyzed." It could mean, as it appears literally, how many molecules, same or not, being analyzed. Or it could mean how many different molecules being analyzed. For example, in a situation where there are two different types of nucleic acid molecules, A and B, being analyzed in a specimen, wherein A and B have different sequences and there are 100 molecules of A and 200 molecules of B being analyzed, it is not clear what n is: 300 (the absolute number of molecules being analyzed) or 2 (the number of different types of molecules).

The phrase "said sample" recited in claims 6, 34 and 47 lack clear antecedent basis, which renders the claims indefinite. Claims 6, 34 and 47 depend from claims 1, 30 and 16, respectively. Independent claims 1, 16 and 30 recite the term "specimen" not "sample." The specification provides distinct meanings for the two terms: " 'specimen' is intended to mean any biological fluid, cell, tissue, organ or portion thereof" (see page 31); and " 'sampler', when used in reference to molecules in a population, refers to a group of molecules in a population having expression levels that are predictive of the health state of an individual" (see page 27).

The metes and bounds of the phrase "substantially similar response" recited in claims 30-32 are not clear. The terms "substantially" and "similar" are relative terms, which render the claims indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. While both terms may be definite in certain situations where guidelines are provided in the specification for ascertaining the scope of the claimed invention (see MPEP 2173.05(b)), in the instant case, the specification does not provide any guideline as to the standard for being "similar" and "substantially similar." Since the responses by different individuals to a particular drug could be vastly different, both qualitatively

and quantitatively, without a clear and definitive guideline in the specification, one of ordinary skill in the art would not be reasonably clear what responses fall into the scope of being "similar" or "substantially similar."

Claim Rejections-35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-2, 4, 6, 8-16, 30-32, 34, 36-44, and 46-55 are rejected under 35 U.S.C. 102 (e)(2) as being clearly anticipated by Friend et al. (P/N 6,218,122).

In the title and abstract, Friend et al. summarizes the monitoring of cellular constituents in connection with therapies. The drug therapy practice perturbs the systems of an individual and thus perturbation response profiles are produced in the disclosure of Friend et al. Figures 1 - 3 depict various multidimensional coordinate point response profiles as in the instant claim limitations. The DETAILED DESCRIPTION section of the reference in column 4, line 46, through column 29, line 39, goes on at length and in detail for such response profile production and analysis. This is also the subject matter of the instant claims with a specific classification of a group of individuals into a drug response population regarding disease states being treated. See, for example, column 6, line 48, through column 8, line 62. Cellular constituents being measured

for such profiles include RNA (nucleic acid) and protein expression as set forth, for example, in column 2, lines 38-47, as also required in the instant claims 11-13, 39-41, and 50-52. The elected specie of the beneficial drug response for alleviating a sign or symptom associated with a disease as in instant claim 4 is also set forth in the reference in column 8, lines 35-39. The basic classification of a population by drug responsiveness as instantly claimed is set forth in the reference in column 9, lines 2-14 and lines 39-47, as monitoring subjects as to efficacy of a drug therapy in a clinical trial. Various molecules may be monitored regarding expression profiles, such as small molecules (instant claims 15, 43, and 54) like glucose as set forth in the reference in column 12, lines 34-41, or antibodies (instant claims 14, 42, and 53) as in the reference in column 12, lines 62-65. An array as a target for cellular measurements is disclosed in column 20, lines 55-59, as in instant claim 10. Leukocyte specimen measurements (as in instant claim 16) are disclosed in the reference via the white blood cell profiling set forth in column 12,lines 31-41.

This rejection is reiterated from the previous Office action mailed 11/17/04 and maintained for reasons of record.

Applicants argue that Friend et al. does not teach the same method as claimed in the instant invention because it does not disclose the new limitation in the claims: creating a multidimensional space of n dimensions, wherein n represents the number of molecules being analyzed. This is not deemed persuasive because Figure 1 of Friends et al. clearly depicts a 2-dimensional space, and 2 is the number of different type of molecules analyzed, i.e. two different copies of the diploid SUN2 gene: the mutant and the wild type. The Declaration under 37 CFR 132 by Hood and Siegel filed 8/24/5 had been considered and responded to in the Office action

mailed 11/17/04. The response retains the same because the new limitation added into the claim does not over Friend et al., as discussed above.

Claim Objections

9. Claims 1-2, 4, 6, 8-16, 30-32, 34, 36-44, and 46-82 are objected to because of the following informalities:

Independent claims 1, 16 and 30 recite "multidmensional" in 3 of each claim, which appears to be misspelled for the word "multidimensional."

Appropriate correction is required.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose phone number is (571) 272-0549.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the

USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shubo (Joe) Zhou, Ph.D.

Patent Examiner

8/21/05

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER